

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
September 2, 2010



**SCHWARZ PHARMA TO PAY 22 MILLION DOLLARS TO
SETTLE CLAIMS BASED ON FDA VIOLATIONS**

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined the states and federal government and reached an agreement in principle with Schwarz Pharma, Inc., a Delaware corporation, and Schwarz Pharma Manufacturing, Inc., an Indiana corporation, (collectively “Schwarz”) to settle allegations that the companies violated FDA regulations concerning the regulatory status of the drugs Deponit and Hyoscyamine Sulfate Extended Release (Hyoscyamine Sulfate ER) and failed to notify the Centers for Medicare and Medicaid Services (CMS) that the drugs no longer qualified for coverage under Medicaid. Schwarz will pay the states and the federal government a total of \$22 million dollars in damages and penalties to compensate Medicaid and various federal healthcare programs for its conduct.

Deponit is a nitroglycerin skin patch that has been used to prevent angina. Hyoscyamine Sulfate ER is an antispasmodic medication that has been used to treat various stomach, intestinal, and urinary tract disorders. While the active ingredients in Deponit and Hyoscyamine Sulfate ER had been in products on the market for many years, the Food and Drug Administration (FDA) made determinations in 1997 and 1999 that resulted in these drugs being ineligible for reimbursement by government healthcare programs such as Medicaid. The states and federal government allege that Schwarz misrepresented the regulatory status of both drugs and failed to advise CMS that these unapproved drugs did not qualify for coverage under federal healthcare programs. As a result, the government contends, Schwarz knowingly caused false claims to be submitted for Deponit and Hyoscyamine Sulfate ER. At no time, did these drugs ever receive full regulatory approval for safety and effectiveness, and neither product is currently on the market.

This settlement is based on *qui tam* cases that were filed in the United States District Court for the Southern District of Texas and the United States District Court of Massachusetts by relators-private parties who filed actions under state and federal false claims statutes.

National Association of Medicaid Fraud Control Units team members participated in the investigation and conducted the settlement negotiations with Schwarz on behalf of the settling states. Team members included representatives from New York, South Carolina, Texas and Maine.